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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/829,504 | 04/21/2004 | David Epstein | 23239-558A (ARC-58A) | 7640 |

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| EXAMINER |
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SCHNIZER, RICHARD A

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| ART UNIT | PAPER NUMBER |
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1635

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 31 DAYS | 03/16/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/829,504 | EPSTEIN ET AL. | |
| | Examiner | Art Unit | |
| | Richard Schnizer, Ph. D. | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4-6 and 17-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 3, 7-16, and 47-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment was received and entered on 1/24/07.

Claims 47-63 were added as requested.

Applicant's election without traverse of group 2, claims 3-16 is acknowledged.

Applicant has withdrawn claims 4-6 from the elected group and declined to elect a SEQ ID set forth in claim 4. This is acceptable, but Applicant is advised that reintroduction of these or other specific sequences later in prosecution may require further restriction.

Claims 1, 2 and 17-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/24/07.

Applicant's amendment necessitates further restriction as set forth below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 3, 7-16 and 47-51 drawn to aptamers comprising a first sequence capable of binding to a first target and a second sequence capable of binding to a second target.
2. Claims 52-63 drawn to an aptamer comprising at least two discrete immunostimulatory motifs, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1 and 2 are drawn to distinct compositions of matter. Invention 1 is drawn to a bivalent aptamer while invention 2 is silent as to this requirement. Invention 2 requires two distinct immunostimulatory sequences. While invention 1 embraces an

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embodiment in which an immunostimulatory sequence is present in the claimed aptamer, invention 1 does not require two immunostimulatory motifs. Further, the immunostimulatory sequence of invention 1 must be capable of binding to a site in a target molecule. The immunostimulatory sequences of invention 2 have no such requirement. The aptamer of invention 2 requires two distinct immunostimulatory motifs, but the aptamer need not be bivalent, and neither immunostimulatory sequence need bind to a site in a target molecule. The immunostimulatory sequences in invention 2 could be appended to an aptamer without being directly involved in binding. Each invention has a separate utility, for example, invention 1 can be used to bind to two different targets simultaneously, whereas invention 2 can be used to bind to a single target. Although the searches for the two inventions could overlap, they are not coextensive, and restriction between them is appropriate due to the search and examination burden.

It is further noted that within group 1, claims 3, 7-16, and 48-51 link 2 inventions set forth in claim 47.

- 1a. Claim 47 is drawn to aptamers comprising a first sequence capable of binding to a first target and a second sequence capable of binding to a second target, wherein the second sequence is an immunostimulatory sequence selected from SEQ ID NOS: 12-16, classified in class 536, subclass 23.1.
- 1b. Claim 47 is drawn to aptamers comprising a first sequence capable of binding to a first target and a second sequence capable of binding to a

second target, wherein the second sequence is an immunostimulatory sequence selected from SEQ ID NOS: 17-19, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Claim 47 is drawn to SEQ ID NOS: 12-19, which are oligonucleotides. SEQ ID NOS: 13-16 are represented within SEQ ID NO:12, and SEQ ID NOS: 18 and 19 are represented within SEQ ID NO:17. Each of these sequences is structurally distinct and would require a separate non-coextensive search. As such the Markush/genus of sequences in the instant claims is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the groups claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed groups. In view of the foregoing, one (1) group of sequences is considered to be a reasonable number of sequences for examination if a group drawn to the Markush group is elected. Note that this is not a species election. However, note also that upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double

patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

A similar relationship exists in group 2 wherein claims 52-55 and 57-62 link 2 inventions set forth in claims 56 and 63.

- 2a. Claims 56 and 63 drawn to an aptamer comprising at least two discrete immunostimulatory motifs wherein the immunostimulatory motif is a CpG motif selected from SEQ ID NOS: 12-16, classified in class 536, subclass 23.1.
- 2b. Claims 56 and 63 drawn to an aptamer comprising at least two discrete immunostimulatory motifs, wherein the immunostimulatory motif is a CpG motif selected from SEQ ID NOS: 17-19, classified in class 536, subclass 23.1.

These groups are distinct for the reasons set forth above, i.e. the sequences of SEQ ID NOS: 12-16 are distinct from those of SEQ ID NOS: 17-19 and require a separate and non-coextensive search, as discussed above. However, upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant asserts at page 14 of the response that the restriction between these sequences is contrary to the guidelines set out in MPEP 803.02 because the sequences are all immunostimulatory sequences. This is unpersuasive because, aside from the presence of the dinucleotide "CG", the two groups of sequences have no structural similarity and require non-coextensive searches.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant inquired at pages 14 and 15 of the response as to whether or not claims 22-24, 26-28, 30-32, 34-36, 38-40, and 42-46, previously objected to as being improperly multiply dependent, might be rejoined with the elected invention. These claims are drawn to methods of using a product. Applicant has elected a product, and the Examiner restricted between products and process in the restriction of 8/24/06.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. Rejoinder will be considered at such time as allowable product claims are identified.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

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dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Richard Schnizer, Ph.D.
Primary Examiner
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